

polio, bone brittleness, and loose dentures, and that the right way to prevent tooth decay is with organic-vegetable and oceanic calcium food.

DISPOSITION: 9-16-58. Default—delivered to the Food and Drug Administration.

5768. Royal jelly capsules. (F.D.C. No. 41486. S. No. 40-761 P.)

QUANTITY: 2 250-capsule btl. and 1 100-capsule btl. at Seattle, Wash.

SHIPPED: 2-6-58, from Los Angeles, Calif., by Healthcraft Products.

LABEL IN PART: "Capsules Healthcraft * * * Jell-E-Vites Royal Jelly * * *
Each capsule contains: Royal Jelly 50 mg. * * * Vitamin B₁₂ * * * 5 mcg. * * *
Vitamin B₁ * * * 5 mg. * * * Vitamin B₆ * * * 1 mg. * * * Calcium Panto-
thenate 5 mg. * * * Niacinamide 10 mg. * * * Vitamin E * * * 5 I.U."

ACCOMPANYING LABELING: Poster of reprints from newspapers and magazines entitled "Famous Newspapers and Magazines Report Sensational Benefits With Royal Jelly."

LIBELED: 3-25-58, W. Dist. Wash.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article would prolong life, cure cancer, rejuvenate failing or worn out glandular activities in human beings, restore vigor, eliminate a feeling of tiredness, restore youthful sex function in women in the menopause, normalize growth of under-developed children, stimulate the appetite, produce a general state of well-being, improve nervous balance, increase virility and sexual energy, have a tonic effect on the mental processes, and cure the ills of old age.

DISPOSITION: 7-9-58. Default—destruction.

5769. Drugs for sex rejuvenation. (Inj. No. 278.)

COMPLAINT FOR INJUNCTION FILED: 2-26-54, S. Dist. Calif., against Wayne A. Parkinson, t/a Glandular Products Co., and also t/a Dybutol Co., Long Beach, Calif.; against Allen H. Parkinson, t/a Tide Mailing Service, Long Beach, Calif.; and against Margaret M. Willis, operating manager of the Tide Mailing Service.

CHARGE: The complaint alleged that the defendants were the interstate promoters and distributors of the following articles: *Adler's Compound* (Standard Strength and Super Strength), consisting of vitamins, minerals, and wheat germ oil in an inert glandular base, *Vita-Glan Male Formula* (Regular Strength and Double Strength), consisting of vitamins in an inert glandular base, and *Bio-Glan Male Formula* (Regular Strength and Double Strength) together with *Bio-Glan Fortified Wheat Germ Oil* consisting of vitamins in an inert glandular base and capsules of wheat germ oil; that the promotion and distribution of such articles was carried out as a mail-order business conducted in the names of the Glandular Products Co., and the Dybutol Co.; that substantially all of the normal business functions of such companies, including the printing, addressing, and mailing of labeling of the articles, the receipt and processing of mail orders for the articles, and the bottling, packaging, labeling, and shipping of the articles, in response to the mail orders, were performed or arranged for by the Tide Mailing Service.

The complaint alleged also that the defendants caused the above-named articles to be introduced into interstate commerce with labeling consisting of the labels on the bottles containing the articles, and of various folders, letters, envelopes, and order forms, including folders, entitled "New Safe Bio-

Glan Male Formula"; "Amazing New Vita-Glan"; and "A Report to Physicians and the Public"; and that the articles were misbranded under 502(a), in that their labeling was false and misleading as follows:

Adler's Compound (Standard or Super Strength)—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article, which was distributed in the United States by Glandular Products Co., was manufactured in Germany and was available in the United States in limited supply only, whereas the article was manufactured in Los Angeles, Calif., on order of the defendants and was available here in unlimited supply;

(c) That the article was a new and amazing medical miracle developed by outstanding German pharmaceutical knowledge and ingenuity, whereas said drug was composed of commonly known ingredients and was not a new and amazing medical miracle;

(d) That the tablets comprising *Adler's Compound* (Super Strength), differed in composition and potency from the tablets comprising *Adler's Compound* (Standard Strength), whereas all of the tablets were identical in composition and potency; and

(e) That distribution of the article was licensed by the person whose photograph appeared on various items of the labeling, and who was identified there as Konrad Adler, a German specialist in glandular research, whereas the photograph was in fact that of a professional model who resided in Hollywood, Calif., years ago, when the photograph was taken.

Bio-Glan Male Formula (Regular and Double Strength), together with *Bio-Glan Fortified Wheat Germ Oil*—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article was marketed by Glandular Products Co., upon the advice and guidance of a medical director, John Garwood, whereas such company had no medical director and the name "John Garwood" was a fictitious one adopted by Wayne A. Parkinson, who was not trained in the field of medicine;

(c) That the tablets comprising *Bio-Glan Male Formula* (Double Strength), had twice the potency of the tablets comprising *Bio-Glan Male Formula* (Regular Strength), whereas all of the tablets were identical in composition and potency; and

(d) That the use of the *Bio-Glan Male Formula* (Double Strength), would create such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of a double-strength anaesthetic ointment to retard the male sexual climax, whereas the use of such drug would not cause any sexual rejuvenation.

Vita-Glan Male Formula (Regular and Double Strength)—the labeling represented and suggested—

(a) That the article was highly efficacious in overcoming male sexual weakness and impotence, whereas it was not efficacious for such purposes;

(b) That the article was highly efficacious in overcoming nervousness, loss of muscle tone, vague aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, and mental dullness, whereas it was not efficacious for such purposes;

(c) That the article was marketed by Glandular Products Co., upon the advice and guidance of a medical director, whereas such company had no medical director;

(d) That the tablets comprising *Vita-Glan Male Formula* (Double Strength), had twice the potency of the tablets comprising *Vita-Glan Male Formula* (Regular Strength), whereas all of the tablets were identical in composition and potency; and

(e) That the use of the *Vita-Glan Male Formula* (Double Strength), would create such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of an anaesthetic ointment to retard the male sexual climax, whereas the use of such drug would not cause any sexual rejuvenation.

The complaint alleged further that if the defendants were forced by an injunction to discontinue their false and misleading labeling, they would, unless further enjoined, continue their promotion and distribution of the above-named articles and similar articles by making claims for sexual rejuvenation through collateral media outside of labeling, and that, in such case, the articles would be misbranded within the meaning of 502(f)(1), in that their labeling would fail to bear adequate directions for use.

The complaint prayed for the entry of a temporary restraining order and a preliminary and permanent injunction, and also for an order directing the defendants to tender to all present and past purchasers of the above-named articles a refund of all amounts collected by the defendants from such purchasers.

DISPOSITION: On 2-26-54, without notice, a temporary restraining order was entered against the defendants; and on 3-11-54, after a hearing, a preliminary injunction was entered against the defendants enjoining them against the acts complained of.

On 11-5-54, the defendants having consented, a decree of permanent injunction was entered against the defendants enjoining them against introducing into interstate commerce any of the above-named articles, similar articles, or other articles offered for similar purposes, that were misbranded as alleged in the complaint. The decree also provided that the question of restitution was specifically reserved and should be subject to subsequent determination by the court.

Following the entry of the decree, briefs on the question of restitution were submitted by counsel, and, on 7-25-55, argument was held before the court on such question. On 10-21-55, the court handed down the following opinion (135 F. Supp. 208):

CARTER, *District Judge*: "This case poses the question as to whether the district court has power to order restitution in an injunction proceeding under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. 331-392; Act of June 25, 1938, Chap. 675, 52 Stat. 1040].

"The case is one of first impression under the Food and Drug Laws, although the problem has been discussed recently in law reviews and journals.¹

¹ Rhyne, *Penalty Through Publicity: FDA's Restitution Gambit*, 7 Food, Drug, Cosmetic L.J. 666-680 (1952)

Noland, *Section 302(a) of the Federal Food, Drug, and Cosmetic Act: Restitution Re-examined*, 7 Food, Drug, Cosmetic L.J. 373-400 (1952)

Lev. *The Nutrilite Consent Decree*, 7 Food, Drug, Cosmetic L.J. 56, 65-67 (1952)

Developments in the Law—The Federal Food, Drug, and Cosmetic Act, 67 Harv. LR 632, 718-720 (1954)

Levine, *Restitution—A New Enforcement Sanction*, 6 Food, Drug, Cosmetic L.J. 503-514 (1951)

Goodrich, *Modern Application of an Ancient Remedy*, 9 Food, Drug, Cosmetic L.J. 565-572 (1954)

"*Restitution in Food and Drug Enforcement*," note in 4 Stan. L. Rev. 519-536 (1952).

"The matter was heretofore heard on an application for a preliminary injunction, and a decree of preliminary injunction was made and entered March 11, 1954. Thereafter a final consent judgment, as to permanent injunction only, was made and entered on November 5, 1954.

"The complaint, in addition to praying for general injunctive relief, prayed 'that the defendants be ordered to tender to all present and past purchasers of the drugs enumerated . . . a refund of all amounts collected by said defendants from said purchasers.' By stipulation of the parties, the question is presented as to whether the district court had discretionary power, ancillary to its jurisdiction to grant injunctive relief under 21 U.S.C.A. 332(a), to compel the defendants to refund to purchasers the money paid for the drugs involved in the action, and whether the court has jurisdiction to issue such an order. The question as to whether the court should *exercise* this power, if it possesses it, is reserved by the stipulation for further hearing if necessary. 21 U.S.C.A. Sec. 332(a) reads:

Injunction proceedings—Jurisdiction of courts (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of Sec. 381 (relating to notice to opposite party) of Title 28, as amended, to restrain violations of section 331 of this title, except paragraphs (e), (f), and (h)–(j). [Act of June 25, 1938, chap. 675, Sec. 302, 52 Stat. 1054]

We are not concerned with the exceptions.

"We start with the axiomatic premise that the district court is one of limited jurisdiction, and has only the power and the jurisdiction spelled out in the statutory enactments of Congress. We exclude from consideration the general equity power of the court called into play in a diversity suit, and also exclude those situations in which, by statute, the Congress has expressly provided that the court may exercise all the powers of a court of equity. We also exclude from consideration the power of a district court to *compel compliance with its orders when violated or threatened to be violated*. (*McComb v. Jacksonville Paper Co.* (1949) 336 U.S. 187, 193) Sec. 332(b), 21 U.S.C.A., expressly makes reference to a violation of the injunction, and proceedings thereon.

"The plaintiffs predicate their argument on analogy to (a) the Rent and Price Control cases, (b) Fair Labor Standard cases, and (c) the Antitrust cases.

1.

The Rent Control cases.

"In *Porter v. Warner Holding Co.* [1946] 328 U.S. 395, the trial court and the court of appeals both held there was no jurisdiction under the statute to order restitution. The Supreme Court reversed. The statute involved was Sec. 205(a) of the Emergency Price Control Act of 1942, 50 U.S.C.A. App. Sec. 925(a) [56 Stat. 23, 33]. It provided that the administrator might apply to the appropriate court . . . 'for an order enjoining such acts or practices, or for an order enforcing compliance with such provision, and upon a showing by the Administrator that such person has engaged or is about to engage in any such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.' [Emphasis added.]

"Sec. 205(a) of the Emergency Price Control Act of 1942 [50 U.S.C.A. App. Sec. 925(a)] first reached the Supreme Court in *Hecht Co. v. Bowles* [1944] 321 U.S. 321. The Supreme Court held that the court could, under the statutory language involved, fashion an appropriate decree to obtain compliance, and at page 328, said:

It seems apparent on the face of § 205(a) that there is some room for the exercise of discretion on the part of the court . . . Though the Administrator asks for an injunction, some "other order" might be more appropriate . . . Such an order, moreover, would seem to be a type of "other order" which a faithful reading of § 205(a) would permit a court to issue in a compliance proceeding.

"In the *Warner Holding* case (*supra*) the Supreme Court, in reversing, rested jurisdiction to issue a mandatory restitution order on two theories, (1) 'as an equitable adjunct to an injunction decree' and (2) 'as an order appro-

appropriate and necessary to enforce compliance with the Act.' (p. 399-400). It said at page 399:

As recognized in *Hecht v. Bowles* . . . the term "other order" contemplates a remedy other than that of injunction or restraining order, a remedy entered in the exercise of the District Court's equitable discretion.

"Both the *Hecht Co. case*, (supra) and the *Warner Holding Co. case*, (supra) considered legislative history of the statute and Sen. Rep. 931, 77th Cong. 2d Session.²

"A portion of the report, quoted in the *Warner Holding Co. case*, (supra) read, 'Such courts are given jurisdiction to issue whatever order to enforce compliance is proper in the circumstances of each particular case.' (p. 401).

"Subsequently, the Supreme Court in *U.S. v. Moore* [1951] 340 U.S. 616, referring to its decision in *Porter v. Warner Holding Co.* (supra), stated, page 619-620:

This Court reversed, concluding that an order of restitution was a proper "other order." This interpretation was required to give effect to the congressional purpose to authorize whatever order within the inherent equitable power of the District Court may be considered appropriate and necessary to enforce compliance with the Act. . . .

Adhering to the broad ground of interpretation of the "other orders" provision adopted in the *Warner case*, we think the order for restitution entered by the District Court in this section was permissible under Section 206(b).³

"We are constrained to believe that *Porter v. Warner Holding Co.* (supra) is authority upon the second proposition, namely that a district court had power to grant an order appropriate and necessary to enforce compliance with the Act, based upon the particular wording of the statute. The other ground was not necessary for the decision. Although considered as dicta, it bears great weight, nevertheless we do not believe that the holding of the *Warner case* should be so extended.

"Since the statute in the case at bar does not contain the reference to 'an order enforcing compliance' or 'other order' we do not consider the rent cases as decisive of our problem.

2.

The Fair Labor Standards cases.

"The Fair Labor Standards Act [29 U.S.C.A. Sec. 201-219] and the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. Sections 301-392] were enacted on the same day. [June 25, 1938, 52 Stat. 1060 and 1040 respectively]. Both statutes contained provisions for equitable relief that were almost identical.⁴

"Several appellate court cases ruled that restitution of back pay could properly be ordered as an adjunct to an injunction under Section 17 of the Fair Labor Standards Act, [Sec. 217 U.S.C.A. Title 29] which required the rehiring of a discharged employee. *McComb v. Frank Scerbo & Sons*, 177 F. 2d 137, 138-139 (C.A. 2, 1949); *Walling v. O'Grady*, 146 F. 2d 422, 423, (C.A. 2, 1949). Cf. *Walling v. Miller*, 138 F. 2d 629 (C.A. 8, 1943) which held that the district court had power to embody a restitution order in a consent decree.

"The Supreme Court, however, never ruled on the question expressly, leaving it open in *McComb v. Jacksonville Paper Co.* [1949] 336 U.S. 187-193.

"But Congress, concerned with the appellate courts' interpretations of Sec. 17 of the Fair Labor Standards Act [Sec. 217, U.S.C.A. Title 29] amended the section to provide in express terms that restitution was not

² The *Hecht* case cited page 25, the *Warner-Holding* case page 10 of the report.

³ *U.S. v. Moore*, involves section 206(b) of the Housing and Rent Act of 1947 as amended. This section contains the same "other order" language found in Sec. 205(a) of the Emergency Price Control Act of 1942, involved in *Porter v. Warner Holding Co.* (supra).

⁴ Section 17 of the Fair Labor Standards Act [52 Stat. 1069]:

"The district courts of the United States and the United States courts of the Territories and possessions shall have jurisdiction, for cause shown, and subject to the provisions of section 20 (relating to notice to opposite party) of the Act entitled 'An act to supplement existing laws against unlawful restraints and monopolies, and for other purposes' approved October 15, 1914, as amended (U.S.C. 1934 edition, title 28, sec. 381) to restrain violations of section 15."

authorized under the section [Act of Oct. 26, 1949, Chap. 736, Sec. 15, 63 Stat. 919] and other statutory provisions were enacted relating to restitution suits.⁵

"This blunt repudiation by Congress of the asserted powers of a district court to order restitution under Fair Labor Standards Act, with its almost identical provisions to that of Sec. 302(a) of the Food and Drug Act [Sec. 332(a) U.S.C.A. Title 21], is significant and convincing insofar as this court is concerned.

3.

The Antitrust cases.

"The Government also relies for authority on the injunction suits to restrain violations of the Sherman Act, [15 U.S.C.A. Sec. 4] where the courts have sustained the remedy of divestiture; and cites *Schine Chain Theatres Inc. v. United States* [1948] 334 U.S. 110, holding divestiture to be an equitable remedy and comparing it to restitution; and *United States v. Paramount Pictures* [1948] 334 U.S. 131 to the same effect.

"We are not convinced. The Sherman Act in Sec. 4 U.S.C.A. Title 15, [Act of July 2, 1890, Chap. 647, Sec. 4, 26 Stat. 209 as amended] provides, 'The several district courts of the United States are invested with jurisdiction to prevent and *restrain* violations of sections 1-7 of this title; and it shall be the duty of the several district attorneys of the United States . . . under the direction of the Attorney General, to *institute proceedings in equity to prevent and restrain* such violations.' [Emphasis added.] This language, read as a whole, clearly empowers the district court with all the remedies of equity. The decisions cited above are then easily understood.

"Nor is divestiture as applied by the courts, the equivalent of restitution. Divestiture requires the defendant to sell his offending interest or stock or properties or to divest himself of his holdings. He is deprived of the offending property at a price. He is not required to restore monies to his competitors by such a decree, though they may, in certain instances, have the remedy of a treble damage suit expressly provided by statute.

CONCLUSION

"There are fundamental differences in purpose between the Rent and Price Control legislation and the Fair Labor Standards Act on the one hand, and the Federal Food, Drug, and Cosmetic Act on the other. They have been well stated by Rhyne, 'Penalty through Publicity; FDA's Restitution Gambit, 7 Food, Drug, Cosmetic L.J. 666-680 [1952],'

The payment of prescribed sums of money is the essence and purpose of the Fair Labor Standards Act, and also of rent and price control laws. Effectuation of the policies of these laws requires the payment of proper sums. But the Federal Food, Drug, and Cosmetic Act is not concerned with payment of money. Its purpose, or as much of it as is relevant here, is to prevent misbranding; that purpose can be accomplished by a restraining order.

"Restitution, apart from its equitable considerations may also be considered punitive. It is a further method of punishing a defendant in that it requires him to pay over monies in his possession to others. There is a line of authorities that 'an injunction is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed,' *High Grade Food Products Corp. v. United States* [8 Cir. 1947] 160 F. 2d 816, and cases cited at page 819; *Minneapolis & St. Louis Ry. Co. v. Pacific Gamble Robinson Co.* [8 Cir. 1950] 181 F. 2d 812 at 814; *American Chiclet Co. v. Topps Chewing Gum* [2 Cir. 1954] 210 F. 2d 680 at 683.

"We conclude that the remedy of restitution is not within the powers of the district court under the statute. The Food, Drug, and Cosmetic Act has pro-

⁵ Sec. 16(c) [21 U.S.C.A. Sec. 216(e)] was amended and Congress thereby created a special statutory pattern designed (1) to permit an independent suit by the Administrator to collect back pay on behalf of employees, and (2) to protect employers from double litigation by declaring that the employee's consent to such suit constituted a waiver of the employee's statutory right to sue in his own behalf.

vided the sanctions of (1) criminal prosecution and punishment of violators, [21 U.S.C.A. Sec. 333], (2) seizure of goods shipped in violation of the Act [21 U.S.C.A. Sec. 334(a)], and (3) injunctions against further violations, [21 U.S.C.A. Sec. 332(a)]. There is no indication in Congressional history that supports any other sanction or specifically the power to order restitution under the Food, Drug, and Cosmetic Act. The contrary was true in the Congressional history of the Emergency Price Control Act.

"The Government's arguments that such power in a district court, is necessary to effect the essential objectives of the Act and to protect the public's pocket-book, should be addressed to Congress, not to a district court. The jurisdiction and power of this court stem not from things necessary or desirable, but from Congressional action.

"The defendants will submit an order denying plaintiff relief under its prayer for restitution. Pursuant to the stipulation of the parties there remains nothing further to be done in this case. This order denying such relief concludes the case and should therefore be final and appealable."

In accordance with the above opinion, an order was entered on 11-15-55, denying the prayer for restitution set forth in the complaint.

An appeal was taken to the United States Court of Appeals for the Ninth Circuit, and on 11-21-56, the following opinion was handed down by that court (240 F. (2d) 918):

FEE, *Circuit Judge*: "This cause was brought at the instance of Food and Drug Administration, Department of Health, Education and Welfare, in the name of the United States of America against the individuals named as defendants, praying that these latter be restrained from introducing into interstate commerce certain misbranded drugs and requiring defendants to make restitution to purchasers thereof, present and past. The claimed misbranding related to relief from male sexual weakness and impotence and to rapid sexual rejuvenation. A temporary restraining order was granted by the trial court and later extended. Subsequently, after the grant of preliminary injunction, there was entered a judgment by which defendants were permanently enjoined and restrained from doing acts in violation of § 301(a) of the Federal Food, Drug, and Cosmetic Act¹ with respect to all these drugs enumerated, 'or other similar drugs, or other drugs offered for similar purposes.' This portion of the judgment was entered by consent. There was also submitted to the court by stipulation the question whether restitution could be required. The trial court, pursuant to stipulation, divided this into two questions: (1) whether the court had power under the statute to order restitution; and (2) whether restitution would be ordered in this particular case.

"It is difficult indeed to see how any relief could be granted in this case. The supposition is that there were purchasers because there were allegations in the complaint of sales in interstate commerce. But no purchaser was named as a party to the action. The United States did not sue as a representative of any purchaser. There is a suggestion in the prayer only that relief be granted by way of restitution. The body of the complaint contains no allegations upon which the suggestion could be supported. There was no evidence introduced either as to identity of purchasers or as to the amount of drugs unlawfully sold. No judgment could be entered for such refunds, if found in favor of the purchasers themselves, because none was a party to the proceeding. No judgment could be entered in their behalf in favor of the United States or the agency. But besides such technical matters, it was demonstrated that the District Court had no jurisdiction to give such relief under the statute.

"In a sound and able opinion, Hon. James M. Carter, United States District Judge, analyzed the problem, reviewed the statutes and determined that the particular enactment did not confer jurisdiction upon the United States District Courts to make such an order.² With this opinion we agree, and the conclusions thereof we affirm. The jurisdiction of the District Court must be found in the language and implications of the particular statute.

¹ 21 U.S.C.A. § 331(a).

² *United States v. Parkinson*, 135 Suppl. 208.

"It is agreed that the history and language of the laws for control of monopolization properly permit the application by the courts of orders requiring divestiture of properties of an existing monopolist in order to prevent the continuance of the evil.³ But the statute⁴ under which such relief was granted was much broader in scope than the legislation under consideration, and further divestiture requires only that defendant sell the offending properties at a price, while in the instant case it is sought to force defendant, who has received a price for property which he sold on a free market, to refund such money to be held for a purchaser who paid it willingly. The courts construed certain language of the Price Control Act⁵ to compel mandatory restitution.⁶ But this legislation was passed and interpreted in time of a struggle for national existence. These laws are now in abeyance and they constitute a doubtful precedent for the extension of enactments such as this which are intended to represent permanent policy in peaceful times as well. These wartime regulations were tremendously unpopular and were deemed arbitrary and oppressive when they were relegated to limbo.⁷ An attempt by the Administrator of the Wage and Hour Division to assert the power of collecting restitution was supported by various courts improvidently.⁸ The congress rebuked this attempt and in effect repealed the supporting decisions by amending the basic act expressly to forbid collection of restitution by the agency.⁹ Since the Fair Labor Standards Act and the Food, Drug, and Cosmetic Act were passed at the same time,¹⁰ an attempt to extend provisions of the latter statute might be similarly rebuked.¹¹ This feature would not prevent a like construction if the language intendment and history of enforcement thereof convinced us it were a pleadable position. But a diametrically opposite conclusion is forced upon us by these factors.

"The Congress granted three specific powers by this Act. The first was the power to bring criminal prosecutions for violations.¹² The second permitted seizure of drugs proscribed in interstate commerce.¹³ The third empowered the courts to restrain violations.¹⁴ Ordinarily, grant of such specific powers would be indicia of the denial of more extensive authority.

³ See Sherman Act of 1890, § 4, 26 Stat. 209, as amended, as construed by *Schine Chain Theatres, Inc. vs. United States*, 334 U.S. 110, 126-130; *United States vs. Paramount Pictures*, 334 U.S. 131, 170-174.

⁴ 15 U.S.C.A. § 4 permits the government "to institute proceedings in equity to prevent and restrain such violations," while the Food, Drug, and Cosmetic Act, § 302, 21 U.S.C.A. § 332, grants to the District Court only "jurisdiction, for cause shown * * * to restrain violations of section 331," § 301 of the Act. [Emphasis added.]

⁵ Emergency Price Control Act of 1942, § 205(a), 56 Stat. 23, 33, 50 U.S.C.A. App. § 925(a), empowering the court to grant upon a proper showing "a permanent or temporary injunction, restraining order, or other order," without bond. [Emphasis added.]

⁶ See *Porter vs. Warner Holding Co.*, 328 U.S. 395, construing the statutory language "other order" to include the remedy of restitution.

⁷ A similar result obtains under a similar Act in *United States vs. Moore*, 340 U.S. 616, construing § 206(b) of the Housing and Rent Act of 1947, as amended, 61 Stat. 199, 50 U.S.C.A. App. § 1896(b). However, this Act, like Price Control, was born of wartime stress. It also provides for local termination upon the expression of such a desire by municipalities by resolution made after hearings. § 204(j)(3), 50 U.S.C.A. App. § 1894(j)(3). A similar choice may be made at the State level. § 204(j)(1), (2), 50 U.S.C.A. App. § 1894(j)(1), (2). The former election has already been made in Dallas, Texas. *United States vs. Moore*, supra.

⁸ See, for example, *McComb vs. Frank Scerbo and Sons*, 2 Cir., 177 F. 2d 137; *Walling vs. O'Grady*, 2 Cir., 146 F. 2d 422.

⁹ The Fair Labor Standards Act of 1938, § 17, 52 Stat. 1069, 29 U.S.C.A. § 217, was amended by the Act of October 26, 1949, 63 Stat. 919, and now reads in pertinent part: "Provided, that no court shall have jurisdiction, in any action brought by the Secretary of Labor to restrain such violations (of 29 U.S.C.A. § 215, entitled in part 'prohibited acts') to order the payment to employees of unpaid minimum wages or unpaid overtime compensation or an additional equal amount as liquidated damages in such action." At the same time, a specific statutory remedy was created, enabling the Secretary of Labor to recover such amounts in any court of competent jurisdiction on behalf of employees to whom such wages were due. Fair Labor Standards Act of 1938, § 16(c), 29 U.S.C.A. § 216(c), as amended by the Act of October 26, 1949, 63 Stat. 919. The authority so conferred was under the most carefully outlined conditions and limitations, which do not exist if this power be conferred by implication from the language of the Food, Drug, and Cosmetic Act.

¹⁰ The Fair Labor Standards Act of 1938, 52 Stat. 1060, et seq., 29 U.S.C.A. § 201, et seq., and the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, et seq., 21 U.S.C.A. § 301, were both passed on June 25, 1938.

¹¹ Especially since § 17 of the Fair Labor Standards Act, 29 U.S.C.A. § 217, before the 1949 amendment, and § 302(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 332(a) are substantially identical.

¹² § 303, 52 Stat. 1043, as amended, 21 U.S.C.A. § 333.

¹³ § 304, 52 Stat. 1044, as amended, 21 U.S.C.A. § 334.

¹⁴ § 302(a), 52 Stat. 1043, 21 U.S.C.A. § 332(a).

"On account of the importance of the subject, it is necessary to deal with certain arguments made upon appeal.

"There is insistently urged upon us the beneficent purposes of the agency, the necessity of protection of the public and the evils of exploitation of the unwary by fraudulent claims as to drugs the use of which may be harmful. Of course, these elements were the factors which motivated the enactment of the statute. Those who drafted the law and secured passage thereof were fully cognizant of the evils at which it was aimed. Unquestionably, there was a subsidiary purpose to protect the purses of the public and to prevent the vending of alleged remedies, which at best were useless, to fatten the pockets of the exploiter. The agents of the government bring forcibly to our attention our own opinion¹⁵ where the court rightly recognized the harm of permitting the introduction into commerce of drugs of this type. They further emphasize the persistence of the individual defendants here, notwithstanding criminal convictions, decrees of restraint and seizure of drugs, in finding new drugs to exploit by false advertising in order to reap a golden harvest for a short time.

"But advertisements of nostrums for restoration of 'Lost Manhood' have appeared in the daily newspapers for at least fifty years in the past. The drafters of the bill and those who engineered its adoption were cognizant of the persistence of those who desired to make money by such means.

"The record of the past few decades is replete with examples of the tendency of executive agencies to expand their field of operations. A passion and a zeal to crusade affects their operations. Strong public opinion may temporarily encourage excesses in zeal. The enforcement of certain measures based upon worthy causes may induce violent reactions. Examples may be found in the enforcement of laws for prohibition of intoxicants and for the rationing of goods in war. These are warning signs that zeal for the noblest causes should not be translated into uncontrolled power of suppression of the contraries. The courts are charged with the duty of compelling restraint.

"It is particularly urged upon us that a court of equity has power to fashion remedies to meet situations and to compel compliance with decrees. To a certain extent this is correct in litigation between private individuals. But Chancery has ceased for long ages to issue new writs whereby supposed wrongs could be cured. Such objectives are modernly to be accomplished only by legislation. Hundreds of years ago, likewise, equity ceased to be the measure of the 'king's foot.' In litigation between private individuals, the course and remedies of equity became standardized, as these had at common law. The growth of precedent delayed improvident and ad lib expansion.

"Equity had, however, developed a great many devices for enforcement of its decrees. But it was with great reluctance that a mandatory decree was entered even in private litigation. Payment of money held in trust might be required. At times, incidental damages were allowed. Penalties were abominated.

"It was not the fashion of the English Crown to use the Chancery as a method of enforcement of regulations and executive orders. Therefore, the precedents in compulsion to accomplish governmental decretals are found rather in the Court of the Star Chamber, of unhappy memory. The case of the Bishops seems to have forecast an end to this development. In our time, through necessity, cases based upon violations of administrative rules and regulations have been brought in courts which have the traditional equity powers and remedies between individuals.

"When Congress authorizes the enforcement by an administrative body, of rules, regulations or orders promulgated by it, the history of equity and the Court of the Star Chamber in this type of litigation should not be forgotten. The use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms. Anything which savors of a penalty should not be permitted unless Congress has expressly so provided, since the spirit of equity abhorred such punitive measures. Here it is apparently contemplated that a judgment be entered in favor of the United States for a definite sum of money for 'restitution.' If the agency were unable or did not give the moneys to the purchasers, it would be covered into the Treasury of the United States.

¹⁵ *United States vs. El-O-Pathic Pharmacy*, 9 Cir., 192 F. 2d 62, 75.

"The collection of moneys not held in trust or earmarked from an individual by an executive department without limitation in amount and without detailed means outlined for disbursement to persons supposed to have paid them constitutes a penalty for violation of a regulation. Indeed, it is with great difficulty, as suggested above, that either the remedy or the word 'restitution' can be twisted or tortured to cover the relief which the agency seeks in this case.

"The holding of the Court is that neither the statute nor any other legislation gives the District Court jurisdiction to grant the relief sought. The equitable powers of the court can not be invoked in the situation because of lack of statutory authority, express or implied.

"We have construed the consent judgment granting injunction and the separate judgment denying so-called 'restitution' as one instrument. The appeal was taken only from the latter part.

"Appeal dismissed."

5770. Skin cream. (F.D.C. No. 42061. S. No. 26-445 P.)

QUANTITY: 143 cartoned jars at Des Moines, Iowa.

SHIPPED: 4-17-58, from New York, N.Y., by Plymouth Cosmetic Corp.

LABEL IN PART: (Jar and carton) "Queen Helene Gift of Life Cream with Placental Substance and Skin Nutritives Vital New Medical Cosmetic Formula Containing Youth-Supporting Biogenic Stimulators * * * Para Labs. New York * * * 4 oz."

ACCOMPANYING LABELING: Carton insert designated "An Exciting Adventure in Turning Back the Clock" and an advertisement from a Des Moines newspaper prepared from a newspaper mat furnished by the shipper and used as part of a counter display in conjunction with the article.

LIBELED: 7-21-58, S. Dist. Iowa.

CHARGE: 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article would act as a skin nutritive; that it would provide biogenic stimulators, youth-producing properties, and the source of life itself; that it would produce a skin that showed no hint of age; and that it would revitalize flabby, loose skin, stimulate circulation, and reinvigorate fibers, bands and cells of the skin.

DISPOSITION: 9-10-58. Default—delivered to the Food and Drug Administration.

5771. DuBarry Creme Natale. (F.D.C. No. 41939. S. No. 26-554 P.)

QUANTITY: 39 cartoned jars at Minneapolis, Minn.

SHIPPED: 5-14-58, from Point Lititz, Pa., by Richard Hudnut.

LABEL IN PART: (Carton) "DuBarry Creme Natale * * * DuBarry Div. New York Paris Net Wt. 1¾ oz." and (jar) "DuBarry Creme Natale * * * Blended with Placentine, New Scientific Discovery made from the Source of Life Itself."

ACCOMPANYING LABELING: Leaflet in carton entitled "Creme Natale Elixir" and display placards designated "New from DuBarry Amazing Preparations."

LIBELED: 7-24-58, Dist. Minn.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article contained a "Vital Substance" which would provide rebirth of the skin, thus enabling the skin to remain in the "bloom" of babyhood; that the article would provide one with a younger appearance and with a look that was "incredibly younger"; that the article would provide both a softening effect and a tightening effect on the skin; that